

Application No. 10/529,636
Reply to Office Action of September 19, 2008

SUPPORT FOR THE AMENDMENTS

Claim 15 has been amended for clarity. Claims 22 and 23 have been canceled.

Accordingly, no new matter is believed to have been added to the present application by the amendments submitted above.

REMARKS

Claims 14-21 and 24-32 are pending. Favorable reconsideration is respectfully requested.

Applicants would like to thank Examiner Welter for the helpful and courteous discussion held with their representative on December 2, 2008. During the discussion, Applicants representative pointed out that Muyle discloses coating with a single mixture of two film-forming coating agents. The following remarks expand on the discussion with the Examiner.

The present invention relates to a method for producing a coated pharmaceutical form or a part of pharmaceutical form or a food supplements or a part thereof by coating a substrate with a mixture of two film-forming coating agents. The two film-forming coating agents are initially separate from one another in the form of a liquid, sprayable aqueous solutions or dispersions, and are simultaneously sprayed by spray application using one or more spray devices which, singly or together, atomize liquids separately, and whose spray beams overlap, to form the coating. See Claim 14.

The rejections of the claims under 35 U.S.C. §103(a) over Mulye in view of Murphy and Pinoit is respectfully traversed. The cited references fail to suggest the claimed process.

Muyle discloses a process in which an insoluble polymer and an enteric polymer are coated on a substrate. See paragraphs [0035]-[0040]. These two components are used as a single composition, i.e., the two polymers are applied from the same solution. See paragraphs [0046]-[0051]. Accordingly, Muyle fails to disclose two film-forming coating agents are initially separate from one another in the form of a liquid, sprayable aqueous solutions or dispersions, and are simultaneously sprayed by spray application using one or more spray devices which, singly or together, atomize liquids separately, and whose spray beams overlap, to form the coating, as claimed.

Murphy discloses a coating process utilizing two sprays of polymer. See columns 2 and 3.

Pinoit describes a laboratory study of polymer blends, and notes that certain polymer polymers are immiscible and incapable of forming a single homogeneous phase. See the Abstract.

One with the cited references in hand would not be motivated to practice the claimed coating process. There is no reason for one to modify Muyle to use two separate solutions each containing one of the coating polymers. The disclosures of Murphy and Pinoit may suggest that combining the coating polymers could be problematic. However, in spite of those teachings, Muyle overcame those difficulties and disclosed a coating process where the insoluble polymer and the enteric polymer could be combined into a single coating composition and used successfully to coat a substrate.

For these reasons, the cited references actually teach away from the claimed process. Murphy and Pinoit suggest that the two coating polymers may not be compatible and Muyle discloses a process using a single composition that manages to avoid the potential problems. This is the complete opposite of the claimed process, in which two different solutions are used.

In addition, Murphy is not in the field of pharmacy but rather in the field of leather chemistry. Thus the technical field of Murphy is different from Muyle.

Murphy is concerned with vapor permeable films which may be used to form a replacement for leather. In contrast to the present application, the films of Murphy need to have a microporous structure in order to be vapor permeable. Such a microporous structure is not applicable to pharmaceutical preparations as disclosed in Muyle. Such coatings need to have a fully closed uniform structure in order to be able to control the release of the coated active pharmaceutical ingredient.

Murphy uses a double spraying technique where a polymer in a solvent is sprayed simultaneously with a solvent in which the polymer is not soluble. There is no second polymer which is incompatible with the first polymer as in the present application. The resulting solvent-non solvent mixture in Murphy induces the microporous structure in the polymer film. Thus in contrast to the present application, Murphy uses the double spraying technique to induce an incompatibility in the spraying solution.

In order to be used as leather replacements the films of Murphy have to be much thicker than coatings for pharmaceutical preparations (example 1, c.6, 1.42 3 – 4 mils; example 2, c.6, 1.53 16 mils, c.2, 1.1, 2 mils to 40 mils or greater..). The substrate of Murphy is never a pharmaceutical pellet but a flat surface likes a glass plate or the like. After spraying of the dispersions on the glass plate, the glass plate and deposited film are immersed in water to remove the residual solvent (DMF). Then the film is dried in an oven at 80 °C and stripped from the glass. The film is found to be porous and rubbery. The vapor transmission is equal to calfskin leather (s. c.6, 1.38-44, example 1). This is completely different from the present application.

The teaching of Pinoit is not in the field of pharmacy but in the field of polymer chemistry. Thus the technical field is different from that of the present application.

Pinoit is concerned with the phase behavior of ternary blends of poly(epichlorohydrin) (PECH), poly(vinyl acetate) and poly(methyl methacrylate). None of these polymers is used in our present application. Of these three polymers only poly(vinyl acetate) is a polymer with pharmaceutical applications. However poly(vinyl acetate) is a neutral polymer and therefore not part of our present application. Poly(methyl methacrylate) is a basic material for transparent mouldings and is not identical with pharmaceutical polymers based on (meth)acrylates. Furthermore the polymer mixtures of Pinoit are not

generated by spraying dispersions but by employing a molder machine and melting the pure polymers at 150 – 180 °C (s.p. 2321 – 2322, “2. experimental”).

Neither Pinoit nor Murphy even if combined with Mulye would motivate a skilled person to arrive at the teaching of our present invention. There is no hint in Murphy to use the double spraying technique in the pharmaceutical field in order to overcome the incompatibility problem of two different polymer dispersions by forcing the sprayed droplets together to form unexpectedly unique fully closed coatings on active ingredient containing pellets as a substrate.

In view of the foregoing, the claimed process is not suggested by the combination of Muyle, Murphy and Pinoit. Accordingly, the pending claims are not obvious over those references. Withdrawal of this ground of rejection is respectfully requested.

During the discussion held on December 2, 2008, the Examiner indicated that the rejection of the pending claims under 35 U.S.C. §112, first paragraph, would be removed. Accordingly, withdrawal of this ground of rejection is respectfully requested.

The rejection of the claims under 35 U.S.C. §112, second paragraph, is believed to be obviated by the amendments submitted above. Accordingly, withdrawal of this ground of rejection is respectfully requested.

Applicants submit that the present application is in condition for allowance. Early notice to this effect is earnestly solicited.

Respectfully submitted,

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